

Lets Move It Feasibility Study to determine if a school-based intervention to increase physical activity and decrease sedentary behaviour among older adolescents is feasible and acceptable

Submission date 23/05/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/06/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/12/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Lack of physical activity is harmful to well-being in adolescence. This is common especially in those with lower educational level, e.g., vocational college degree, compared to those who attended high schools. Schools are promising places for interventions (implement methods) to increase physical activity, as youth spend a major part of their day there. This study aims to find out whether a program to increase physical activity and reduce sitting is acceptable and feasible to be conducted in a vocational college.

Who can participate?

Teachers with health education courses among comparable educational tracks in the participating school are enrolled in this study. The students are about 16-19 years old. The core class teachers of the four classes are invited to participate in the classroom sitting reduction programme after training.

What does the study involve?

The four classes are randomly allocated to one of two groups: control and intervention. The students in the intervention group receive a 6-hour group-based programme that aims to increase their physical activity motivation and self-regulation skills. The core class teachers of the students enrolled in the intervention group receive two 2-hour training workshops to improve their motivation and skills to reduce their students sitting in class.

What are the possible benefits and risks of participating?

Benefits are increase physical activity, well-being and reduce risks associated with inactivity. There are no risks or side effects expected from the programme.

Where is the study run from?

The programme is implemented in one of the vocational colleges in the Southern Finland.

When is the study starting and how long is it expected to run for?

The study started in April 2014 and runs until December 2014.

Who is funding the study?

Ministry of Social Affairs and Health and Ministry of Education and Culture of Finland.

Who is the main contact?

Dr Nelli Hankonen

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

201310238

Study information

Scientific Title

Cluster-randomised controlled feasibility study of a school-based multi-level intervention to increase physical activity and decrease sedentary behaviour among older adolescents

Study objectives

The aim of the proposed study is to test the feasibility and acceptability of the intervention, to test measurement and trial procedures for a future Cluster-Randomised Controlled Trial of a

newly developed school-based behaviour change intervention amongst 15-19-year-old adolescents in vocational colleges. More specifically:

1. To determine the feasibility of conducting a definitive cluster-RCT of an intervention program to increase physical activity and reduce sedentary behaviour in vocational colleges.
2. To use data arising from differences between intervention and control arm to inform a power calculation for sample size of a definitive RCT.
3. To estimate trial recruitment (percentage of students/teachers who consent to the trial) and completion/retention rates (percentage of participants completing the trial).
4. To embed a process evaluation within the pilot trial to assess the acceptability of the intervention and trial procedures for students and teachers, with a focus on the student participants with lowest activity levels and highest body fat mass at baseline:
 - Assess acceptability of recruitment, randomisation and consent procedure
 - Assess acceptability and feasibility of collecting reliable and valid data on primary and secondary outcomes (acceptability of measurement instruments)
 - Assess acceptability of length of intervention and intervention content and materials
 - Assess appropriateness/suitability of the intervention used
 - Assess barriers to attendance or use
 - Assess perceived impact on well-being and potential harmful effects
 - To evaluate narratives about the causal model of the intervention

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Hospital District of Helsinki and Uusimaa, The Ethics Committee for gynaecology and obstetrics, pediatrics and psychiatry

Study design

Pilot outcome assessor blinded cluster-randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Physical activity and sitting behavior

Interventions

1. Intervention / Students: The intervention focuses on changing physical activity behaviours, in a sample of vocational school students. A researcher will deliver six group sessions. Groups will include 10-20 participants. The introduction of behaviour change techniques will follow a logical pattern with a discussion of the beliefs, barriers and facilitators related to physical activity in participants lives, then goal setting, action planning and self-monitoring in subsequent sessions, followed by the introduction of subsequent techniques (e.g. feedback on the behaviour) on a weekly basis concluding with relapse prevention towards the end of the intervention. After the group sessions, consenting participants will be given short booster sessions by the researcher delivering the intervention, via email and/or by phone.

Control group (standard care plus written information on physical activity from UKK-Institute): Participants in the control group will receive a leaflet after completing baseline questionnaires.

2. Intervention / Teachers: Intervention is based on: two workshops, where teachers are motivated and trained to use different techniques to reduce students sitting during classes, a webpage and equipment provided in the classroom to enable more activity for the students. Teachers will be introduced to the behavior change techniques such as goal setting, action planning, scheduling and monitoring behavior, followed by practice of these techniques. After the first workshop teachers receive a detailed manual, to increase motivation to reduce students sitting and to rehearse their skills to use different techniques to interrupt sitting. The second workshop helps the teachers plan how to overcome potential barriers and provides further methods for sitting reduction. The teachers are provided with the chance of further individual support from the researchers.

Control group (written information): Participants in the control group will receive a leaflet informing them about the benefits of breaking sitting.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Feasibility and acceptability of study procedures and intervention materials

Secondary outcome measures

1. Physical activity (accelerometer and self-reported): baseline, 6-week follow-up, 6 month-follow-up

2. BMI: baseline and 6-month follow-up

3. Body composition: muscle mass and fat mass (Tanita bioimpedance measurement): baseline and 6-month follow-up

4. Social and psychological determinants of behavior: baseline, 6-week follow-up, 6 month-follow-up

Overall study start date

04/04/2014

Completion date

31/12/2014

Eligibility

Key inclusion criteria

Vocational students and their core class teachers whose classes involve a large amount of sitting

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

60 students, 20 teachers

Key exclusion criteria

Students:

1. Insufficient knowledge of the Finnish language to take part in group interventions and use written materials
2. Medical conditions preventing participants from engagement in physical activities.

Teachers:

1. Mostly teaching in classrooms/workshops which do not involve sitting

Date of first enrolment

04/04/2014

Date of final enrolment

31/12/2014

Locations**Countries of recruitment**

Finland

Study participating centre

Social Psychology Unit

Helsinki

Finland

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Sponsor information**Organisation**

University of Helsinki (Finland)

Sponsor details

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Sponsor type

Government

ROR

<https://ror.org/040af2s02>

Funder(s)

Funder type

Government

Funder Name

Ministry of Social Affairs and Health (Finland); ref. 201310238

Funder Name

Ministry of Education and Culture (Finland); ref. 34/626/2012

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/03/2017	17/12/2020	Yes	No